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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,054	02/05/2002	William F. McDonald	044829-0118	6271

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/068,054

Applicant(s)

MCDONALD ET AL.

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10-27-03 and 12-23-03.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 8-12, 24-47 and 57-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 13-23 and 48-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/5/02; 7/30/03 & 12/23/03
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Response to Election Requirement of 9-24-03 is acknowledged.

Applicant's election without traverse of Species 1, sub-species C, dated 10-27-03 is acknowledged.

In response to election requirement, applicants state that claims 1-7, 13-23 are included in species 1 and that the process claims corresponding to species 1 include 24-32, 36-44 and 48-59. Further, applicants' state that claims 1 and 13-23 as well as claims 24-28, 36-40 and 48-52 are generic with respect to the polymers designated in the office action. Further, applicants identified that claims 48-59 correspond to the process sub-species C. However, claims 1-7, 13-23 and 48-56 have been considered for prosecution as they read on the elected species and subspecies i.e., species1, subspecies C. Claims 8-12, 24-47 ad 57-59 have been withdrawn as being non-elected.

### ***Specification***

Examiner notes that instant specification recites pending application, by title and filing date. Examiner requests that the information regarding US patent applications be updated.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 and 13-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 059112070 (JP) in view of US 5,135,811 to White et al ('811) or in view of US 6,365,066 to Podszun et al ('066).

Instant claim 1 requires polymeric composition having antimicrobial properties comprising a crosslinked chemical combination of a polymer having side chains along a backbone forming the polymer and at least two of the side chains containing an amino group, an antimicrobial agent of a markush group and a cross linking agent containing at least 2 functional groups capable of reacting with the amino groups. Claim 2 recites the process of preparing polyamide by reacting a monomer selected from unsaturated carboxylic acid, their esters etc., and first amine to form an intermediate product, which is reacted with second amine to form the polyamide. Instant specification recites cross-linking agents such as glutaraldehyde, formaldehyde and phosphine for cross-linking.

JP teaches manufacture of antibacterial polyamide fibers and their blends comprising treating polyamide fibers with anionic phenol an antibacterial agent. JP teaches nylon 66, which is a polyamide produced by condensation of adipic acid and hexamethylenediamine (see Hawley's' condensed chemical dictionary, page 811), treated with antibacterial dichlorophenoxyphenol. Thus, the polyamide of JP (nylon 66), meets the requirement of claim 2 (process of producing polyamide). The antibacterial of JP reads on the antimicrobial phenol compounds of instant claims. The abstract of JP does not mention cross-linking of polymer and antimicrobial.

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'811 teach polyamide yarn provided with built in antibacterial properties comprising quaternary ammonium antimicrobial agents. '811 teach applying quaternary ammonium antimicrobial agent on the polyamide yarn and heat fixing the antimicrobial on the polyamide for stabilization (col. 3, L 43-50).

'066 teach anti-fouling compositions comprising biocidal compounds such as antimicrobials, antifungal or anti-algal compounds encapsulated within polymeric microspheres. '066 teach natural or synthetic polyamide, polyesters, polyurethane etc., as the suitable polymers or even crosslinked polymers such as gelatin (a natural polyamide) (paragraph bridging col. 6-7). '066 further teach cross-linking gelatin polymer with chemical crosslinkers such as glutaraldehyde, formaldehyde etc (col. 7, L 12-14 and L 27-46).

Thus, '811 compositions containing combination of polyamide polymers and antimicrobial agent, where the polymer and the antimicrobial agent are produced by heat fixing for stabilization, and '066 teach cross linking polyamide polymer with chemical compounds (that are also described in the instant specification). Thus, cross-linking by employing heat or chemicals is art recognized. Although, '811 and '066 fail to recognize the claimed phosphine cross linking agent, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to perform cross linking by using heat or employ any known chemical cross linking agents with an expectation to stabilize the polyamide and antimicrobial agent of JP. Further, '066 teaches a number of antimicrobial agents, including the claimed iodine compounds, quaternary ammonium compounds, phenol derivatives etc., as suitable antimicrobial agents. Accordingly, incorporating a suitable antimicrobial agent in the polyamide fibers of JP and still

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expecting an optimum antimicrobial effect would have been obvious for a skilled artisan at the time of the instant invention.

Claims 48-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 059112070 (JP) in view of US 5,135,811 to White et al ('811) or in view of US 6,365,066 to Podszun et al ('066) as applied to claim 1-17 and 13-23 above, and further in view of US 5,328,698 ('698).

JP does not teach the claimed process of rendering a surface of a substrate antimicrobial. '732 teach medical articles of a polymeric substrate that is coated with a composition that includes a bioactive agent in a matrix. '698 teach coating of substrates with polymer is a conventional process and teach substrate made of polyester, polyamide, polyurethane etc (col. 4, L 10-23). Among bioactive agents, '698 teach anti-microbial agents such as phenolic, biguanidines, cetyl pyridinium etc (LINES BRIDGING COL. 4-5). Further, '698 teach dissolving the bioactive (if soluble) in the matrix or dispersing in the matrix and applying or coating it on the polymeric substrate. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the polyamide –antimicrobial fibers of JP for coating polymeric substrates (of medical devices) that are made of polyurethane, polyesters etc., with an expectation to render the devices antimicrobial or anti-infective.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 13-23 and 48-56 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 20-25, 45, 47, 49-51 and 53-62 of copending Application No. 09/850,324. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant and the copending claims recite a polymeric composition having antimicrobial properties comprising a polymer, an antimicrobial agent and a cross linking agent. Both sets of claim recite the same process of preparing the claimed polyamide polymer. Although the antimicrobial agents of instant claims are different from that of the co-pending claims, the comprising language of the instant claims allow for the presence of the antimicrobial agents of the copending application. Further, adding a suitable antimicrobial agent with an expectation to achieve an antimicrobial effect would have been obvious to a skilled artisan at the time of the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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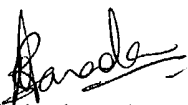
***Minor Informalities***

Instant claims 1, 2, 5-7, 13, 15 48-53 and 55-56 recite the markush groups as “selected from”. It is suggested to applicants to amend the phrase to “selected from the group consisting of”.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala  
Examiner  
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March 8, 2004



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